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(54) **Alignment guide**

(57) An alignment guide (1) for use in femoral head surgery comprising:

a support member (2);

a cannulated rod (16) supported by, and adjustable with respect to, the support arm, and

two jaws, a superior jaw (5) and a inferior jaw (6), each jaw having a proximal end connected to the support, and a distal end for clamping to the neck of the femur in use; at least one of said jaws being movable from a first open position to a second clamping position.

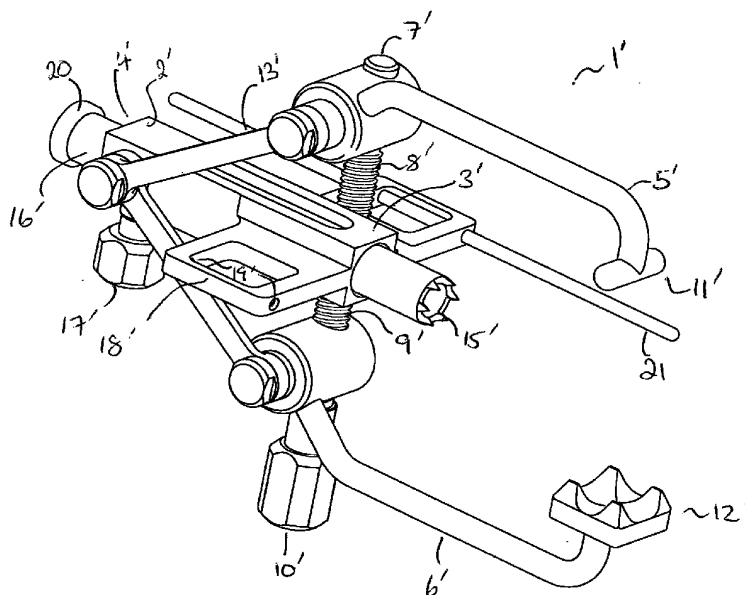


Figure 3

Description

[0001] The present invention relates to a tool for use in hip resurfacing operations. More particularly, it relates to a head alignment tool.

[0002] The efficient functioning of the hip joints is extremely important to the well being and mobility of the human body. Each hip joint is comprised by the upper portion of the upper leg bone (femur) which terminates in an offset bony neck surmounted by a ball-headed portion which rotates within a socket, known as the acetabulum, in the pelvis. Diseases such as rheumatoid- and osteo-arthritis can cause erosion of the cartilage lining of the acetabulum so that the ball of the femur and the hip bone rub together causing pain and further erosion. Bone erosion may cause the bones themselves to attempt to compensate for the erosion which may result in the bone being reshaped. This misshapen joint may cause pain and may eventually cease to function altogether.

[0003] Operations to replace the hip joint with an artificial implant are well-known and widely practiced. Generally, the hip prosthesis will be formed of two components, namely: an acetabular, or socket, component which lines the acetabulum; and a femoral, or stem, component which replaces the femoral head. During the surgical procedure for implanting the hip prosthesis the cartilage is removed from the acetabulum using a reamer such that it will fit the outer surface of the acetabular component of the hip prosthesis. The acetabular component can then be inserted into place. In some arrangements, the acetabular component may simply be held in place by a tight fit with the bone. However, in other arrangements, additional fixing means such as screws or bone cement may be used. The use of additional fixing means help to provide stability in the early stages after the prosthesis has been inserted. In some modern prostheses, the acetabular component may be coated on its external surface with a bone growth promoting substance which will assist the bone to grow and thereby assist the holding of the acetabular component in place. The bone femoral head will be removed and the femur hollowed using reamers and rasps to accept the prosthesis. The stem portion will then be inserted into the femur.

[0004] In some cases, a femoral component of the kind described above may be replaced with components for use in femoral head resurfacing or for use in thrust plate technology.

[0005] Although the prosthesis being inserted when the head is being replaced or resurfaced or in thrust plate arrangements is relatively small, the requirement for the surgeon to obtain the necessary access to the hip joint means that it is necessary to make a large incision on one side of the hip. In one technique, a straight incision is made through the skin on the posterior edge of the greater trochanter. In some techniques this incision may be made when the hip is flexed to 45°. By

known techniques, the muscles and tendons are parted and held by various retractors such that they do not interfere with the surgeons access to the hip joint. The hip is then dislocated to provide access to the head of the femur.

[0006] It will be acknowledged that it is essential that the replacement surface for the head of the femur should be precisely located in both angular and translation positions of the axis of the femoral neck of the implant. To assist this, in some techniques, the surgeon inserts a pin in the lateral femur. The desired position of the pin will be known from pre-operative analysis of the x-rays. The surgeon will measure the desired distance down the femur from the tip of the greater trochanter and the alignment pin is inserted through the vastus lateralis fibres. The alignment pin is inserted in a transverse direction into the mid-lateral cortex and directed upwardly towards the femoral head. The pin is left protruding so that an alignment guide can be hooked over the alignment pin. Suitable alignment guides include those known as the McMinn Alignment Guide available from Midland Medical Technologies Ltd.

[0007] Prior art alignment guides of the kind described above generally comprise a hook or aperture which is placed over the alignment pin thus providing a good angular position for the axis of the implant in valgus, varus and ante-version of the neck. The guide will then be adjusted such that a cannulated rod is located such that the aperture therein is directed down the mid-lateral axis of the femoral neck. A stylus having been set to the desired femoral component size is positioned such that it can be passed around the femoral neck. When the stylus can be passed around the femoral neck, the cannulated rod is locked in position. Once the guide is stabilised in this way fine adjustments can be made until the surgeon is happy that the guide is in the required position.

[0008] A guide wire can then be inserted through the cannulated rod. This guide wire is then used in the further surgery in which the femoral head is shaped to accept the prosthesis. It will be understood that the alignment guide is an essential tool in the surgical procedure to ensure that the aperture drilled in the femoral head is both central to the femoral neck and at the correct angle of alignment to the femoral neck and that the shaping of the femoral head is accurate for the chosen head size.

[0009] It will therefore be understood that it is very important that the alignment guide is positioned correctly. Failure to do so may have the disastrous effect of allowing the machining of the cylinder of the head during the shaping procedure to "notch" into the neck of the femur. This will predispose the bone to early failure on load bearing.

[0010] Whilst the prior art alignment tools are particularly suitable for their function and have reached a high level of acceptance among surgeons, there is now a move towards a less invasive surgery in which the required incision should be as small as possible and the

amount of interaction with healthy tissue is minimised. It is therefore desirable to consider carrying out femoral head replacement or resurfacing without the need to insert the alignment pin. Thus it is desirable that all of the surgical procedure takes place at the femoral head. There is therefore a requirement for an alignment guide which can function without interaction with an alignment pin.

[0011] Other guides are known which are, in use, located on the femoral neck itself. These are used in a similar manner to those described above and may involve some adjustment by the surgeon before he selects the best position.

[0012] In addition, it is desirable that the overall function and safety of the alignment guide be improved. It is further desirable that the alignment guide facilitates the accuracy and ease of use of the instruments that work from the neck.

[0013] Thus according to the present invention there is provided an alignment guide for use in femoral head surgery comprising:

a support member;
a cannulated rod supported by, and adjustable with respect to, the support arm; and
two jaws, a superior jaw and an inferior jaw, each jaw having a proximal end connected to the support and a distal end for clamping to the neck of the femur in use; at least one of said jaws being movable from a first open position to a second clamping position.

[0014] The alignment guide is configured such that in use the jaws in the first open position may be passed over the head of the femur and in the second clamping position will clamp against the neck of the femur.

[0015] In a preferred arrangement both jaws will be movable from the first open position to the second clamping position.

[0016] The two jaws will preferably each be movable by the operation of a screw means. Whilst each jaw may have a dedicated screw means, in a preferred arrangement the jaws will be mutually connected at their proximal ends via a screw member having two oppositely threaded ends, each threaded end being associated with a jaw such that when the screw is rotated in one direction the jaws will move towards the center of the screw to the clamped position and when it is rotated in the other direction the jaws move apart to the open position. It will be understood that in this arrangement the jaws remain parallel during the movement between the open and the clamped position.

[0017] The screw means having two oppositely threaded ends will be connected to the support member by any suitable arrangement. In one arrangement where the screw means is the screw member having oppositely threaded ends, the center portion of the screw member, which may be unthreaded, will pass through a re-

ceiving portion of the support member.

[0018] The screw means will preferably include a head to facilitate the operation of the screw means by the operator.

[0019] To improve stability of the tool, the jaws may be connected to the support member by pivot arms.

[0020] The jaws may be curved along at least a part of their length such that in use they can extend around the head of the femur and their distal ends can be clamped to the neck of the femur. Alternatively a portion of the length will be substantially straight and in this arrangement, a portion, towards the end of the jaws, remote from the support member will be angled to allow the distal ends to clamp to the neck of the femur.

[0021] The tool will preferably be configured such that one jaw is particularly suitable for clamping to the inferior part of the neck (i.e. the underside) and can therefore be referred to as the inferior jaw, and the other is particularly suitable for clamping to the superior part of the neck (i.e. the topside) and can therefore be referred to as the superior jaw.

[0022] The two jaws may be of the same or different configurations. Biting elements may be located on one or both jaws to improve the clamping of the jaw with the neck of the femur.

[0023] The biting element on the superior jaw may be of any suitable arrangement but is preferably a T-bar located at or near the distal end of the jaw. In use the T-bar will come into contact with the superior part of the neck. The T-bar is preferably cylindrical.

[0024] Whilst the jaws may each be of any suitable length, the inferior jaw may be longer than the superior jaw. In one arrangement, the inferior jaw may extend in length over the superior jaw to provide a flag to assist the surgeon to visually ensure that the tool is in the required position. This distal portion of the inferior jaw may be substantially straight.

[0025] Where a biting element is located on the inferior jaw, it may be of any suitable configuration. In one arrangement it may be a toothed block. The block may have a concave face between the teeth. The block may comprise four teeth, the teeth will preferably be configured and spaced on the block such that in use they interact with the inferior part of the neck of the femur to cause the tool to be angled at the optimum position. Thus the teeth will enable the tool to be clamped at the correct anteversion angle and at the correct angle from the sagittal plane with these angles being fixed by the femur itself. It is generally believed that there is a portion of the inferior femoral neck located from the head/neck junction of the femur to a position about 2 cms from the head/neck junction which is parallel to the optimum angle for the positioning of the stem of the prosthesis and hence this is often used as an alignment reference.

[0026] The optimum position of the tool may be achieved with four teeth in a generally square configuration. The teeth are preferably spaced at from about 10 to about 25 mm apart. They are most preferably spaced

at about 15 mm

[0027] In the arrangement where the four teeth are provided in a generally square configuration, the length of the inferior jaw, or the positioning of the block on the inferior jaw will be selected such that the teeth will interact with the portion of the femoral neck detailed above.

[0028] The correct axis for insertion of the guide wire into the head of the femur is approximately 30 degrees from the sagittal plane and in 20 degrees anteversion. Thus the jaws and biting elements are configured such that in use the cannulated rod will be located such that a guide wire is inserted at the correct angle. In the most preferred arrangement of the present invention the tool will automatically take the correct orientation from the medial neck.

[0029] The cannulated rod is adjustable with respect to the support member. In one arrangement, the rod is a sliding fit in the support arm. Once in the required position the cannulated rod will preferably be lockable such that once locked further movement is prevented. The locking means may be of any suitable arrangement. In one arrangement, a locking screw may be used.

[0030] The cannulated rod will in use enable the surgeon to position the guide wire. The cannulated rod may have a slot extending along at least a part of the length of the rod to assist in removing the tool from the guide wire once it is in position.

[0031] The cannulated rod will preferably have teeth located at the distal end thereof which in use can be driven into the surface of the femoral head. When driven into the head, these teeth help to clamp the alignment tool in position and to stabilise the tool.

[0032] The cannulated rod may additionally function as a measuring or gauging device and to assist this the surface of the rod may include measuring indicia to assist the surgeon to know how deep they have cut.

[0033] An alignment rod support may be included on the support arm which may support one or more alignment rods which in use will provide a visual guide to assist the surgeon to check that the tool is in the correct position.

[0034] The or each alignment rod, which may be of any suitable arrangement, may be fitted into the alignment rod support by any suitable arrangement. One or more apertures may be included in the alignment rod support through which a portion of the alignment rod may be passed. The alignment rod may be a guidewire.

[0035] The tool of the present invention may additionally include stylus means of the kind known in the prior art.

[0036] The correct axis for insertion of the guide wire into the head of the femur is approximately 30 degrees from the sagittal plane and in 20 degrees of anteversion. Thus the tool of the present invention is configured such that in use the cannulated bore will be located such that the guide wire is inserted at the correct angle. The arrangement of the present invention allows the surgeon to visually check that the tool is in the correct orientation.

[0037] In femoral head resurfacing techniques, the surgeon will shape the head of the femur to fit within the cavity of the resurfacing prosthesis. This generally involves a number of shaping steps including the removal of the dome of the femoral head by means of a saw. It is important that the saw cut is made in the correct position so that an accurate fit with the prosthesis can be achieved.

[0038] The position of the cut to remove the dome of the femoral head can be calculated from the top of the dome of the femoral head. Thus a saw cutting guide may be located on the cannulated rod such that when the rod is in position, the guide will illustrate the correct position for the cut. Separate guides may be provided for each head size of resurfacing head prosthesis.

[0039] In an alternative arrangement, a saw cutting guide may be located on at least one of the jaws.

[0040] The alignment guide of the present invention may be used in combination with an elongate distal alignment guide which is described in more detail below.

[0041] The alignment guide of the present invention may be used in a method of preparing the head of a femur for femoral head resurfacing wherein the method comprises:

exposing the head of a femur;
locating the alignment guide according to the above first aspect on the neck of the femur; and
machining the head of the femur.

[0042] During the surgery, a well may be drilled into the head of the femur via the collar or rod. This well may be the definite hole diameter required of approximately 8 mm and drilled to a depth determined by the tube touching the head. A check may be made with a stylus once the tool is removed and cylinder cutters used guided over a peg placed in the well. These cutters are arranged such that the diameter cut will be correct for the head size chosen and will bottom on the top of the cut head such that the teeth of the cutter do not dangerously over-sail the head-neck junction and cause soft tissue damage or neck notching.

[0043] Thus the method preferably comprises:

exposing the head of the femur;
locating the alignment guide according to the above first aspect on the neck of the femur;
inserting a drill through the collar and drilling a well into the head of the femur;
removing the drill;
removing the alignment guide;
removing the top of the head of the femur;
inserting a guide rod into the well;
locating a sleeve cutter on guide rod and cutting the head; and
optionally chamfer cutting the head.

[0044] The correct axis for insertion of the guide wire

into the head of the femur is approximately 30 degrees from the sagittal plane axis of the femur and in anteversion to allow for the natural offset in each position. Thus the tool of the present invention is configured such that in use the cannulated bore will be located such that the guide wire or drill is inserted at the correct angle. The arrangement of the present invention allows the surgeon to place, and to visually check that the tool is in the correct orientation, and position centered on the femoral head-neck junction.

[0045] It will be understood that whilst the tool of the present invention offers particular advantages for minimal invasive surgery, it can also be used in conventional surgical techniques.

[0046] The tool of the present invention may be used with all sizes of resurfacing head.

[0047] The present invention will now be described by way of example with reference to the accompanying figures in which:

Figure 1 is a perspective view of the tool of the present invention;

Figure 2 is a side view of the alignment tool of Figure 1 in use;

Figure 3 is a perspective view of an alternative configuration of the present invention;

Figure 4 is a side view of the alignment tool of Figure 3 in use;

Figure 5 is a schematic illustration of the alignment guide of the present invention in combination with an elongate distal alignment guide showing alignment with the femur;

Figure 6 is a schematic illustration of the alignment guide of the present invention in use in combination with the elongate distal alignment guide located against the middle of the back of the knee;

Figure 7 is a perspective view of the arrangement of Figure 5; and

Figure 8 is an enlarged detail of V of Figure 7.

[0048] As illustrated in Figure 1, the alignment tool 1 of one embodiment of the present invention comprises a support arm 2 having a distal end 3 and a proximal end 4.

[0049] A superior jaw 5 and an inferior jaw 6 are attached to a screw means 7 which comprises a screw member having two oppositely threaded ends 8 and 9 and a head 10. When the head is rotated in one direction the jaws 5 and 6 move inwardly to the clamped position and when rotated in the other direction the jaws 5 and 6

move outwardly to the open position. During movement of the jaws, they remain mutually parallel.

[0050] The jaws of this embodiment are curved along at least a part of their length. In the illustrated embodiment, the inferior jaw 6 is longer than the superior jaw 5 to form a flag 6a which is straight.

[0051] The biting means on the superior jaw 5 is a cylindrical T-bar 11 which is located at the end of the jaw and perpendicular thereto.

[0052] The biting means on the inferior jaw 6 is a toothed block 12 which is located on the straight portion of the jaw.

[0053] The jaws are additionally connected to the support means 2 by pivot arms 13.

[0054] The cannulated rod 16 is a sliding fit in a sleeve in the support means. A locking screw 17 will enable the user to lock the cannulated rod at the required position. A bore will extend through the rod. Teeth 15 are located on the face of the bore.

[0055] A flag holder 18 having apertures 19 through which a flag such as a guide wire may be passed.

[0056] The tool of the first embodiment of the present invention in the clamped position on the neck of a femur is illustrated schematically in Figure 2.

[0057] An alternative arrangement is illustrated in Figure 3. The alignment tool 1' of this second embodiment of the present invention comprises a support arm 2' having a distal end 3' and a proximal end 4'.

[0058] A superior jaw 5' and an inferior jaw 6' are attached to the screw means 7' which comprises a screw member having two oppositely threaded ends 8' and 9' and a head 10'. When the head is rotated in one direction the jaws 5' and 6' move inwardly to the clamped position and when rotated in the other direction the jaws 5' and 6' move outwardly to the open position. During movement of the jaws they remain mutually parallel.

[0059] The jaws of this embodiment are substantially straight along at least a part of their length and are then angled such that in use their ends can interact with the neck of a femur. In the illustrated arrangement, a flag corresponding to 6a in the embodiment of Figure 1 is not present. However, it will be understood that the arrangement of Figure 3 could readily be adjusted to include the flag if required.

[0060] The biting means on the superior jaw 5' is a cylindrical T-bar 11' which is located at the end of the jaw and perpendicular thereto. The biting means on the inferior jaw 6' is a toothed block 12'. The teeth are located about 15 mm apart and as illustrated in Figure 4 interact with the substantially straight portion of the inferior part of the neck of the femur.

[0061] The jaws are additionally connected to the support means 2' by pivot arms 13'. The cannulated rod 16' is a sliding fit in a sleeve in the support means. A locking screw 17' will enable the user to lock the cannulated rod at the required position. A bore will extend through the rod. Teeth 15' are located on the face of the bore.

[0062] A flag holder 18', which in this embodiment is arranged to hold up to two guide wires is provided. The flag holder 18' has apertures 19' through which a flag such as a guide wire 21' may be passed.

[0063] The tool of this embodiment of the present invention in the clamped position on the neck of the femur is illustrated schematically in Figure 4.

[0064] The alignment guide of the present invention may be used in combination with an elongate distal alignment guide 120. The elongate distal alignment guide 120 is illustrated in Figures 5 to 8. The elongate distal alignment guide is used to suggest an optimum femoral component angle for the resurfacing head implant. The alignment guide of the present invention suggests an angle for insertion of the guide wire and ultimately the final implanted femoral resurfacing head prosthesis, relative to the leg alignment axis. The leg alignment axis is a theoretical line between the centre of the femoral head, middle of the knee and middle of the ankle when the person is standing. The axis can be measured easily between the femoral head and knee on a patient in surgery. The position of the axis and the femoral component angle are illustrated in Figure 5.

[0065] The elongate distal alignment guide may be attached to the alignment guide of the present invention or it may be a separate component which may be connectable to the alignment guide of the present invention or separate therefrom. Where it is separate, it will touch on the elongate guide of the present invention to measure the current femoral component angle.

[0066] As illustrated in Figure 6, whether the elongate alignment guide is fixed or separate it will generally comprise a long rod 121 slidable in a collar 122 so that its length can be adjusted. A locking nut 123 will be provided to lock the rod at the desired length. A stop 124 may be provided at the end of the rod which in use will come into contact with the back of the patient's knee to protect the skin. Arms 125, 126 extend from the collar 122 and enable the rod to be either fixed to the alignment guide of the present invention or impinge therewith. Arm 126 may be referred to as a probe arm. The angle between the rod 121 and the probe arm 126 may be fixed or it may be adjustable. An adjustable arrangement is illustrated in more detail in Figures 7 and 8. In Figure 8, the "+" sign implies that the alignment guide of the present invention needs to be placed more in valgus and the "-" implies that it needs to be placed in more varus. The area shown hatched in Figure 8 is the area that is free to rotate on the shaft until it touches on the alignment guide of the present invention. In an alternate arrangement, the "+/-" display may be placed with a display showing degrees.

[0067] In use, the spiked end 127 should be placed at the centre of the femoral head as this represents the start of the leg alignment axis.

[0068] It will be understood that the elongate distal alignment guide described above may be used with any alignment guide of the present invention or any other

alignment guide.

Claims

1. An alignment guide for use in femoral head surgery comprising:
 - a support member;
 - a cannulated rod supported by, and adjustable with respect to, the support arm, and
 - two jaws, a superior jaw and a inferior jaw, each jaw having a proximal end connected to the support, and a distal end for clamping to the neck of the femur in use; at least one of said jaws being movable from a first open position to a second clamping position.
2. An alignment guide according to Claim 1 wherein both jaws are movable from the first open position to the second clamping position.
3. An alignment guide according to Claim 1 or 2 wherein the jaws remain parallel as they move from the first open position to the second clamping position.
4. An alignment guide according to any one of Claims 1 to 3 wherein the two jaws will each be movable by a screw means.
5. An alignment guide according to Claim 4 wherein the two jaws are mutually connected at their distal ends via a screw member having two oppositely threaded ends.
6. An alignment guide according to Claim 5 wherein the center portion of the screw member passes through a receiving portion of the support member.
7. An alignment guide according to Claim 6 wherein the center portion of the screw is unthreaded.
8. An alignment guide according to any one of Claims 5 to 7 wherein the screw means includes a head to facilitate rotation of the screw means.
9. An alignment guide according to any one of Claims 1 to 8 wherein the jaws are connected to the support member by pivot arms.
10. An alignment guide according to any one of Claims 1 to 9 wherein the jaws are curved along at least a part of their length.
11. An alignment guide according to any one of Claims 1 to 9 wherein the jaws are straight along at least a part of their length.

12. An alignment guide according to any one of Claims 1 to 11 wherein the two jaws are of different configurations.
13. An alignment guide according to any one of Claims 1 to 11 wherein biting elements are located on one or both jaws to improve the clamping of the jaw with the neck of the femur. 5
14. An alignment guide according to Claim 13 wherein the biting element on the superior jaw is a T-bar located at or near the proximal end of the jaw. 10
15. An alignment guide according to Claim 13 or 14 wherein the biting element on the inferior jaw will be a toothed block. 15
16. An alignment guide according to Claim 15 wherein the block has a concave face between the teeth. 20
17. An alignment guide according to Claim 15 or 16 wherein there are four teeth in a square configuration.
18. An alignment guide according to Claim 17 wherein the teeth are about 15 mm apart. 25
19. An alignment guide according to any one of Claims 1 to 18 wherein the cannulated rod is adjustable with respect to the support arm. 30
20. An alignment guide according to Claim 19 wherein the rod is a sliding fit in the support arm.
21. An alignment guide according to Claim 19 or 20 wherein the tool additionally includes means for locking the cannulated rod with respect to the support member. 35
22. An alignment guide according to any one of Claims 1 to 21 wherein the alignment guide additionally includes a saw cutting guide. 40
23. An alignment guide according to any one of Claims 1 to 22 wherein the alignment guide additionally includes a flag holder. 45
24. A kit comprising the alignment guide of any one of Claims 1 to 23 and an elongate distal alignment guide which by referencing the back of the knee will reference the leg alignment axis. 50

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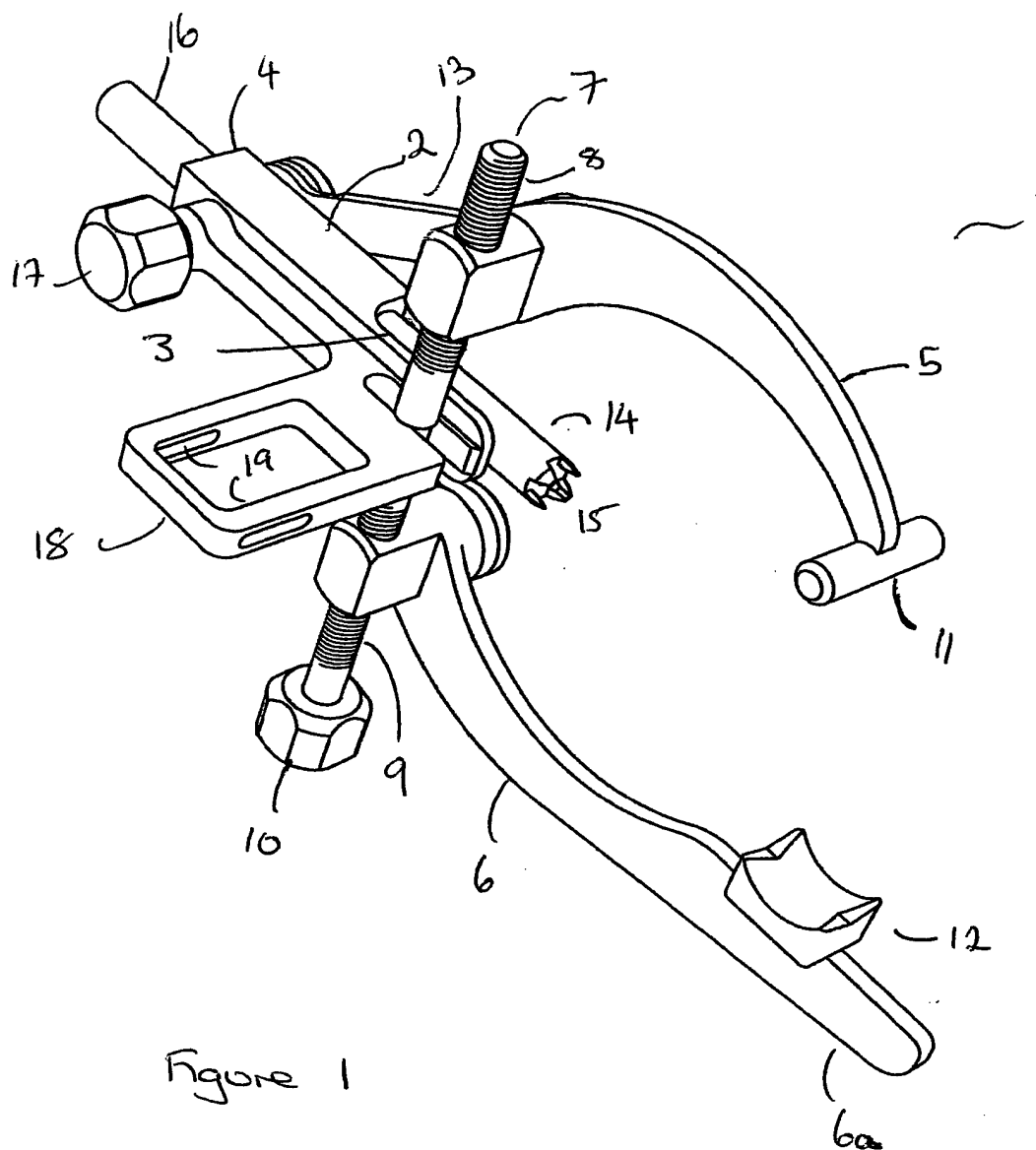


Figure 1

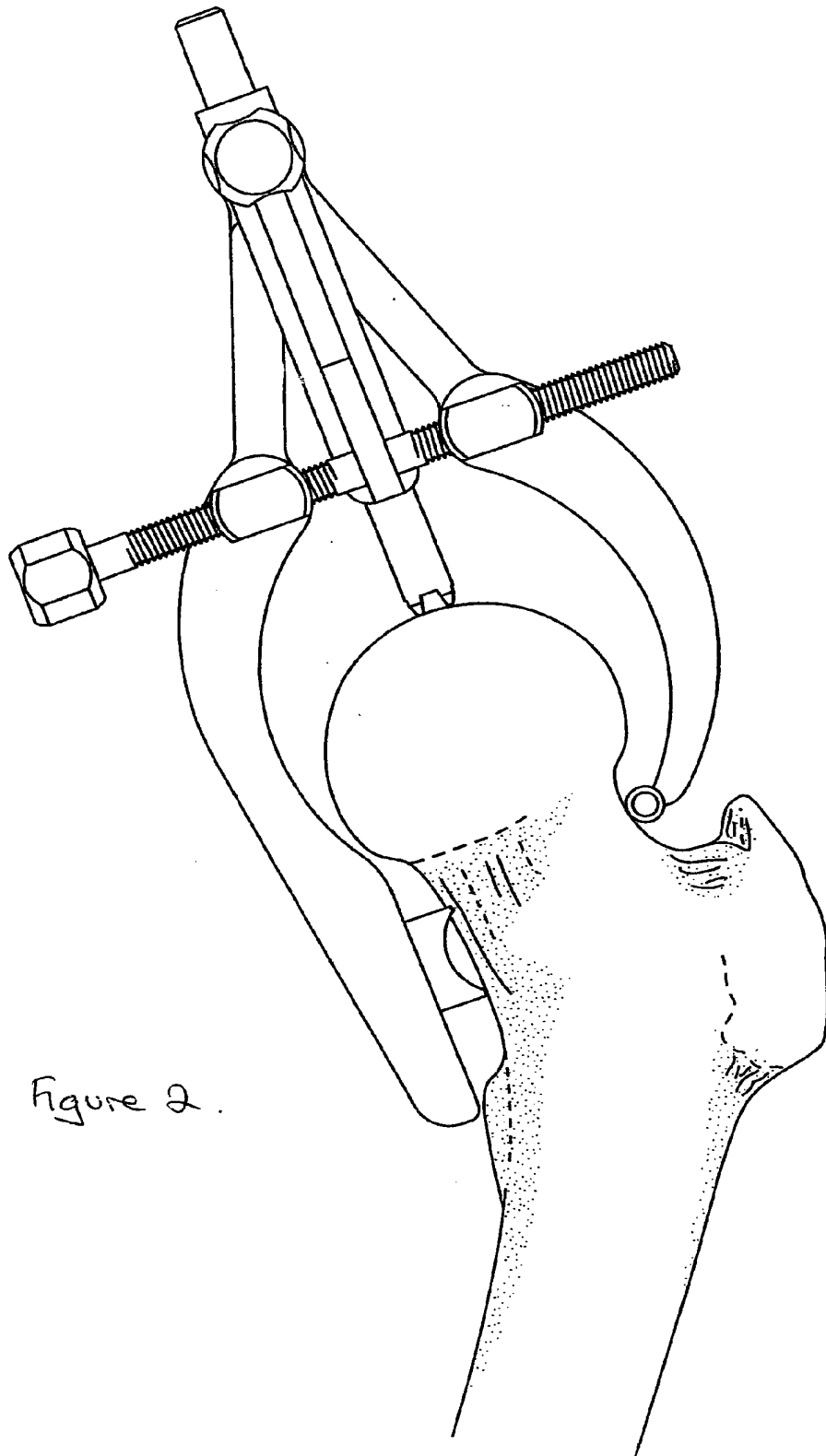


Figure 2.

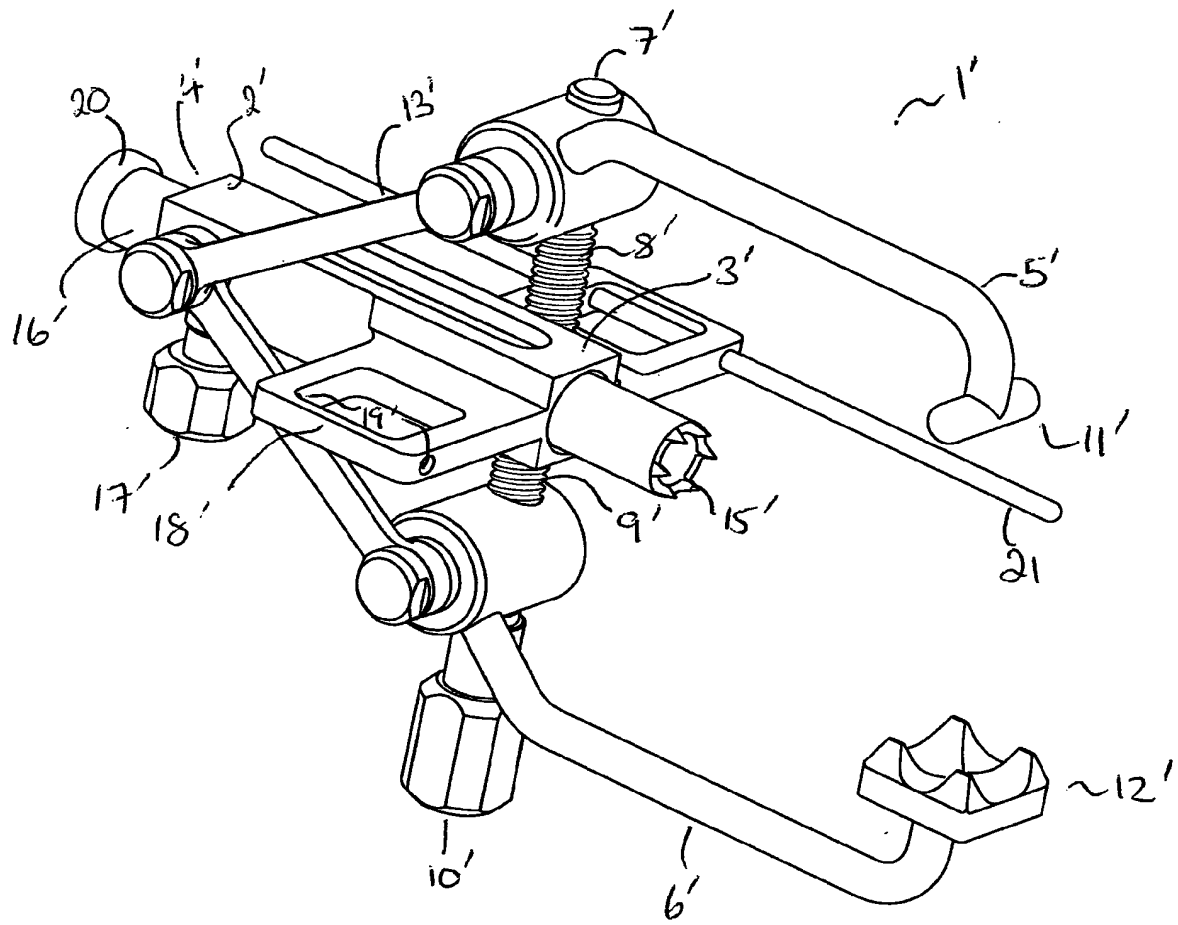


Figure 3

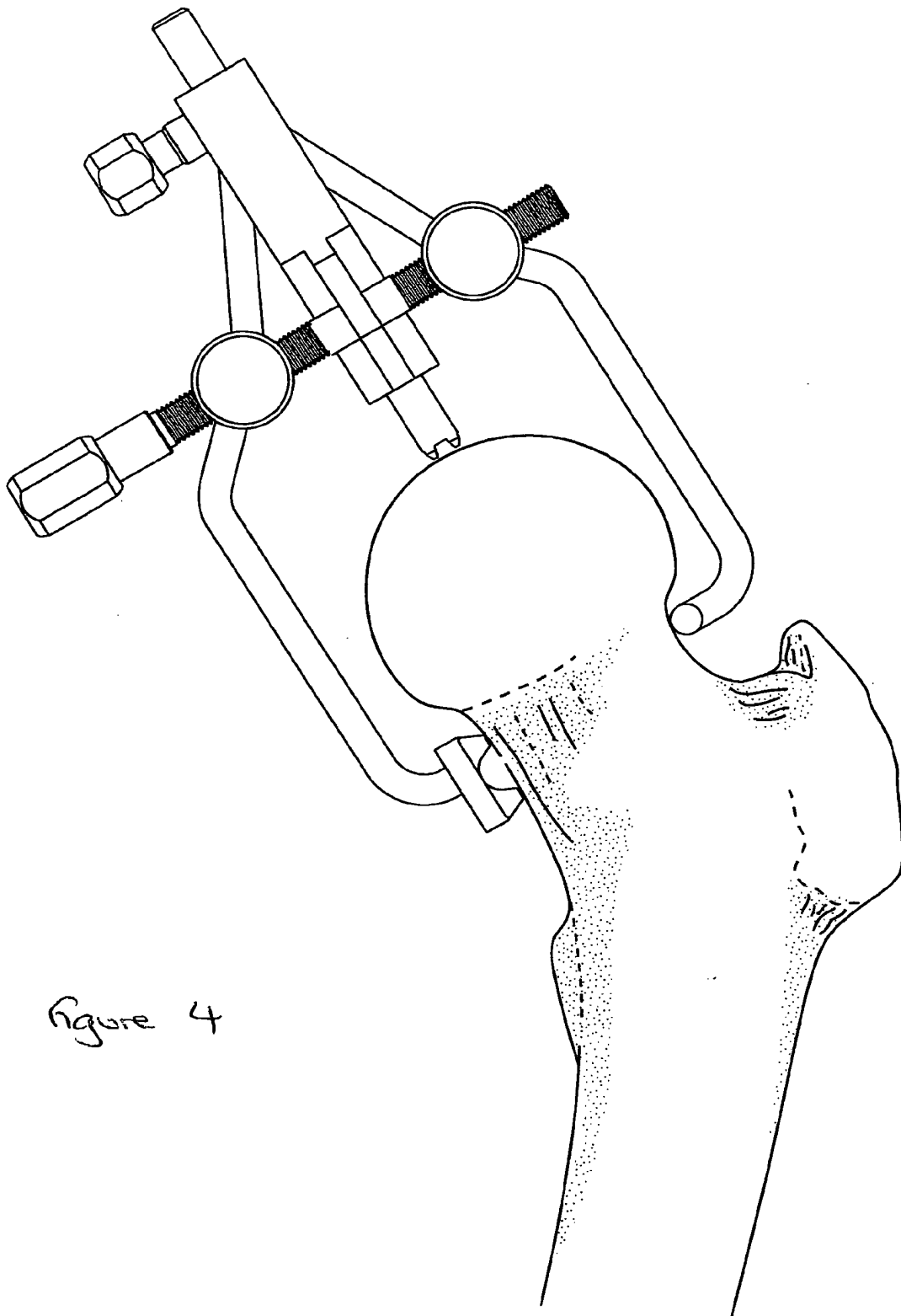
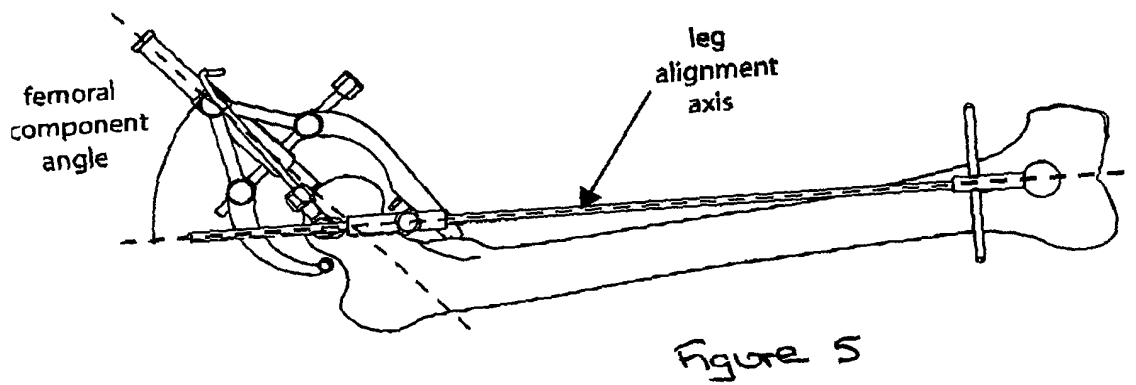
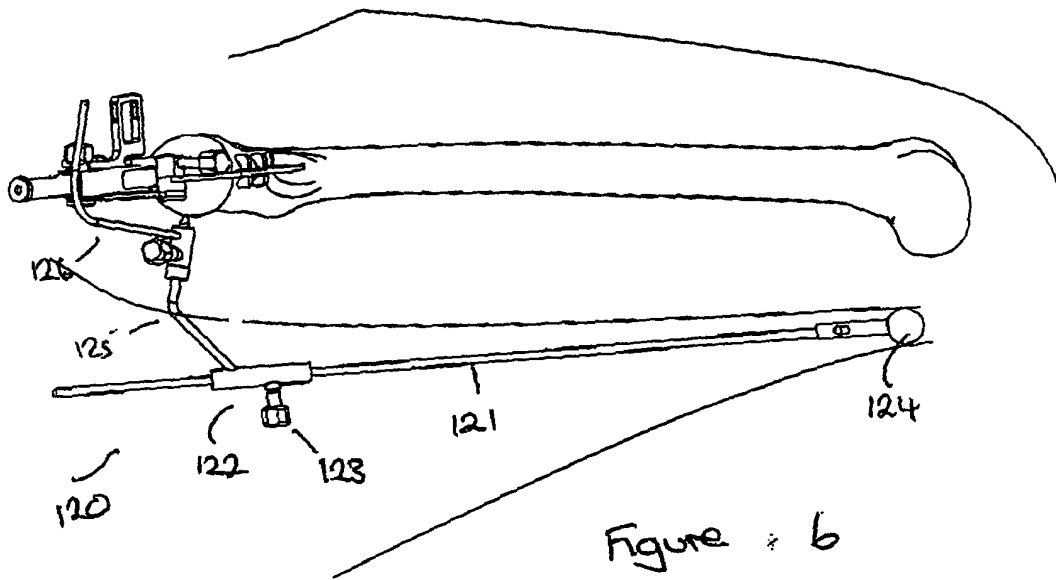
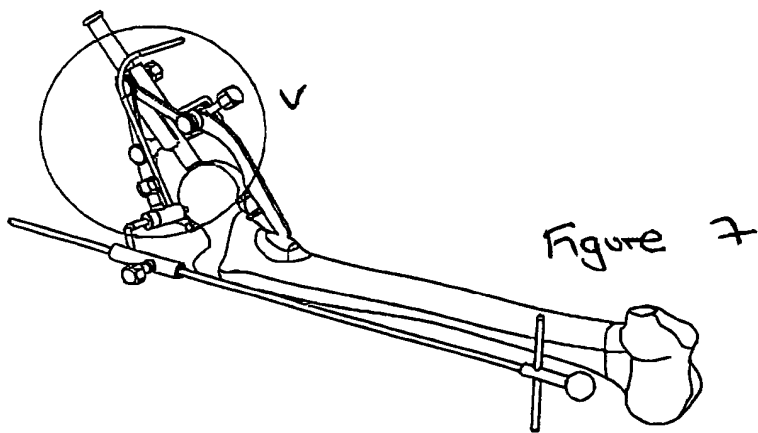
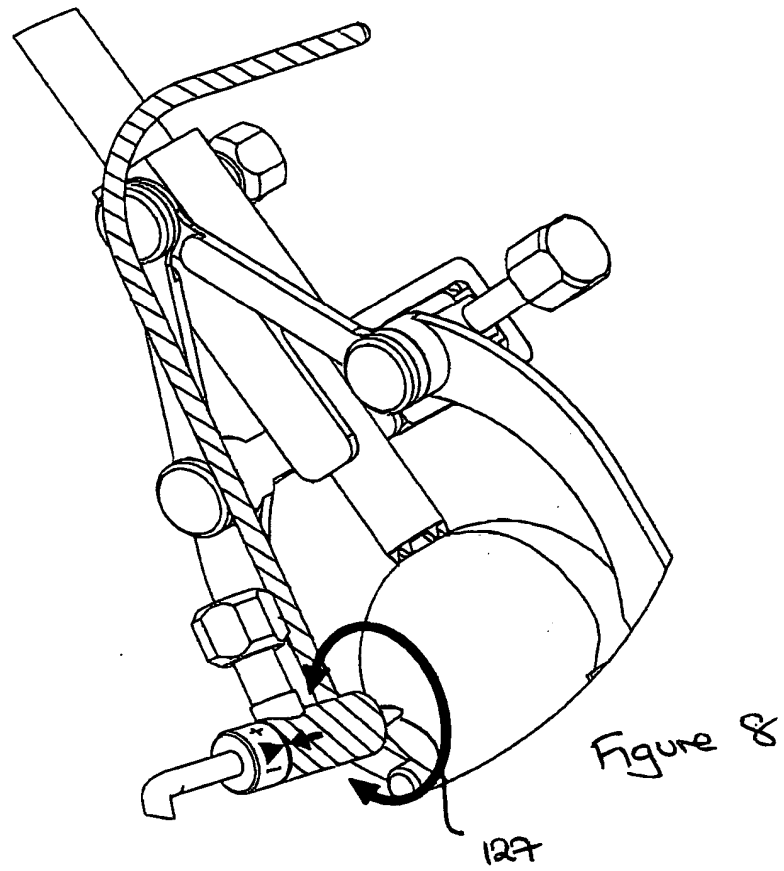


figure 4







European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 05 25 2477

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	US 6 156 069 A (AMSTUTZ ET AL) 5 December 2000 (2000-12-05) * column 5, line 45 - line 56 * * figure 9 *	1,2,10, 13,14, 19,20	A61B17/17 A61B17/16 A61B17/15
Y	----- US 4 896 663 A (VANDEWALLS ET AL) 30 January 1990 (1990-01-30) * column 2, line 44 - column 5, line 7 * * figures 1,3,8 *	3-5,8,9	
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			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61B B66C
The present search report has been drawn up for all claims			
Place of search Munich		Date of completion of the search 12 July 2005	Examiner Storer, J
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

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EPO FORM 1503 03.82 (F04C01)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 05 25 2477

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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12-07-2005

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US 5312409	A	17-05-1994	NONE	
DE 10013331	A1	20-09-2001	NONE	
GB 2303713	A	26-02-1997	NONE	